

Appln. No. 10/585,374
Reply dated August 24, 2009
Reply to Office Action of June 24, 2009

REMARKS

Claims 1-3, 6, 7, 15, 27, 31-34, 40-42, 47, 49, 61-64, 73-76, 84 and 115, 120 and 121 presently appear in this case. No claims have yet been examined on the merits. All of the claims have been subject to restriction and election requirements. Subject to the traversal below, claims 2, 3, 7, 15, 33, 40-42, 47, 49, 61- 63, 64, 73-76, 84 and 121 have been withdrawn from consideration. Reconsideration and withdrawal of the restriction requirement and prompt consideration on the merits of all of the claims now appearing in the case are hereby respectfully requested.

The examiner has required restriction to one of the following Groups under 35 U.S.C. 121 and 372:

- I. Claims 1-3, 6, 7, 15, 27, 31-34 and 115-121, drawn to a medical device and kit.
- II. Claims 40-42, 47, 49, 61-64, 73-76 and 84, drawn to a method of manufacturing a medical device.

This restriction requirement is respectfully traversed.

Traverse to the restriction of the Group I and II above:

Subject to the following grounds for traversal, in order to be responsive, applicant hereby elects the claims of Group I, including claims 1-3, 6, 7, 15, 27, 31-34 and 115-121.

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Applicant respectfully traverses the restriction of Groups I and II because the claims of Group II are method of manufacturing claims of the device of Group I. Under PCT Unity of Invention rules, the amended claim 40 and its dependent claims (Group II), must be examined together with claim 1 and its dependent claims (Group I). This is because all of the claims share the same special technical feature. See MPEP 1893.03(d), where it states:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

Claim 40 has been amended to be dependent on claim 1. Claim 1 is a device claim and claim 40 is a method of manufacturing the device of claim 1.

Claim 1 of the present invention claims the following:

1. A medical device for implantation in a vessel, comprising at least one anastomotic member at least partially interposing a non-woven liner of electrospun fibers and a non-woven cover of electrospun fibers; said at least one

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anastomotic member being designed for engaging at least one end of the medical device to a wall of the vessel upon implantation of the medical device within the vessel.

40. *A method of manufacturing a medical device in accordance with claim 1, the method comprising: providing at least one anastomotic member designed for engaging a wall of the vessel; electrospinning a first liquefied polymer on a precipitation electrode, thereby providing a non-woven liner of electrospun fibers; mounting said at least one anastomotic member onto said precipitation electrode; and electrospinning a second liquefied polymer on at least one of: said precipitation electrode, said non-woven liner and said at least one anastomotic member, so as to provide a non-woven cover of electrospun fibers.*

The method of manufacturing in claim 40 is adapted to manufacture two main parts of the anastomotic member. The parts are:

1. A non-woven liner of electrospun fibers; and,
2. A non-woven cover of electrospun fibers.

These two parts are the main novel elements of the present invention, and both are clearly mentioned in claim 1 and claim 40. Therefore, the method of manufacturing of the present

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invention in claim 40 is relevant to the specific device of the present invention in claim 1.

It is respectfully submitted that the method of manufacturing the device claimed in 40-42, 47, 49, 61-64, 73-76 and 84 (Group II) are not disclosed in US patent application 2004/0030377 mentioned by the Examiner. US patent application 2004/0030377 discloses a method and apparatus for manufacturing fiber shells via electrospinning. This patent application does not disclose "anastomotic member at least partially interposing a non-woven liner of electrospun fibers and a non-woven cover of electrospun fibers". Hence, the device and the method of manufacturing of the device of the present invention are novel and comprise an inventive step in the light of US patent application 2004/0030377.

Accordingly, the method claims share a special technical feature with the product claims and accordingly, restriction is improper and should be withdrawn.

Furthermore 37 CFR 1.475(b)(1) states:

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

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(1) A product and a process specially adapted for the manufacture of said product;

MPEP 1893.03(d) states in this regard:

A process is "specially adapted" for the manufacture of a product if the claimed process inherently produces the claimed product with the technical relationship being present between the claimed process and the claimed product. The expression "specially adapted" does not imply that the product could not also be manufactured by a different process.

Thus, regardless of whether or not there is a special technical feature that defines over the prior art, a process specially adapted for the manufacture of the claimed product must be examined together with the product claims. They are "considered to have unity of invention." Reconsideration and withdrawal of the restriction requirement are therefore respectfully urged.

In the Office Action, the Examiner determines that the application is directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species A: Figs. 1a-1b

Species B: Fig. 2a

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Species C: Fig. 2b

Species D: Fig. 3

[Applicant notes that the examiner skipped Species E]

Species F: Figs. 4a-4b

Species G: Fig. 6

Moreover, the examiner determines that the claims of the application are deemed to correspond to the species listed above in the following manner:

Species A: Claim 3

Species B: Claim 2

Species C: Claim 7 and 121

Species D: Claim 15

Species F: Claims 6 and 120

Species G: Claim 15

Applicant provisionally elects species F, claims 1, 6, 27, 31, 32, 33, 34, and 115-120 for prosecution purposes, without traverse. Accordingly, applicant hereby elects temporarily withdraws claims directed to species A, B, C, D, and G, that comprise the claims 2, 3, 7, 15 and 121, from prosecution, without prejudice. However, applicant notes the examiner's statement that upon allowance of a generic claim, applicant will

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be entitled to consideration of claims to additional species which are written in dependent form.

In the Office Action, the examiner further states that all of the species A-G above include the following Subspecies:

Subspecies 1: Claim 32.

Subspecies 2: Claim 33.

Applicant provisionally elects Subspecies 1, claim 32 for prosecution purposes, without traverse. Applicant hereby temporarily withdraws claims 33 of Subspecies 2 from prosecution, without prejudice. However, applicant notes the examiner's statement that upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form.

Accordingly, reconsideration and withdrawal of the restriction requirement and examination on the merits and

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allowance of all of the claims now present in the case are hereby earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: /rlb/
Roger L. Browdy
Registration No. 25,618

RLB:edg
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528